



ARMED SERVICES BLOOD PROGRAM UPDATE UBCC

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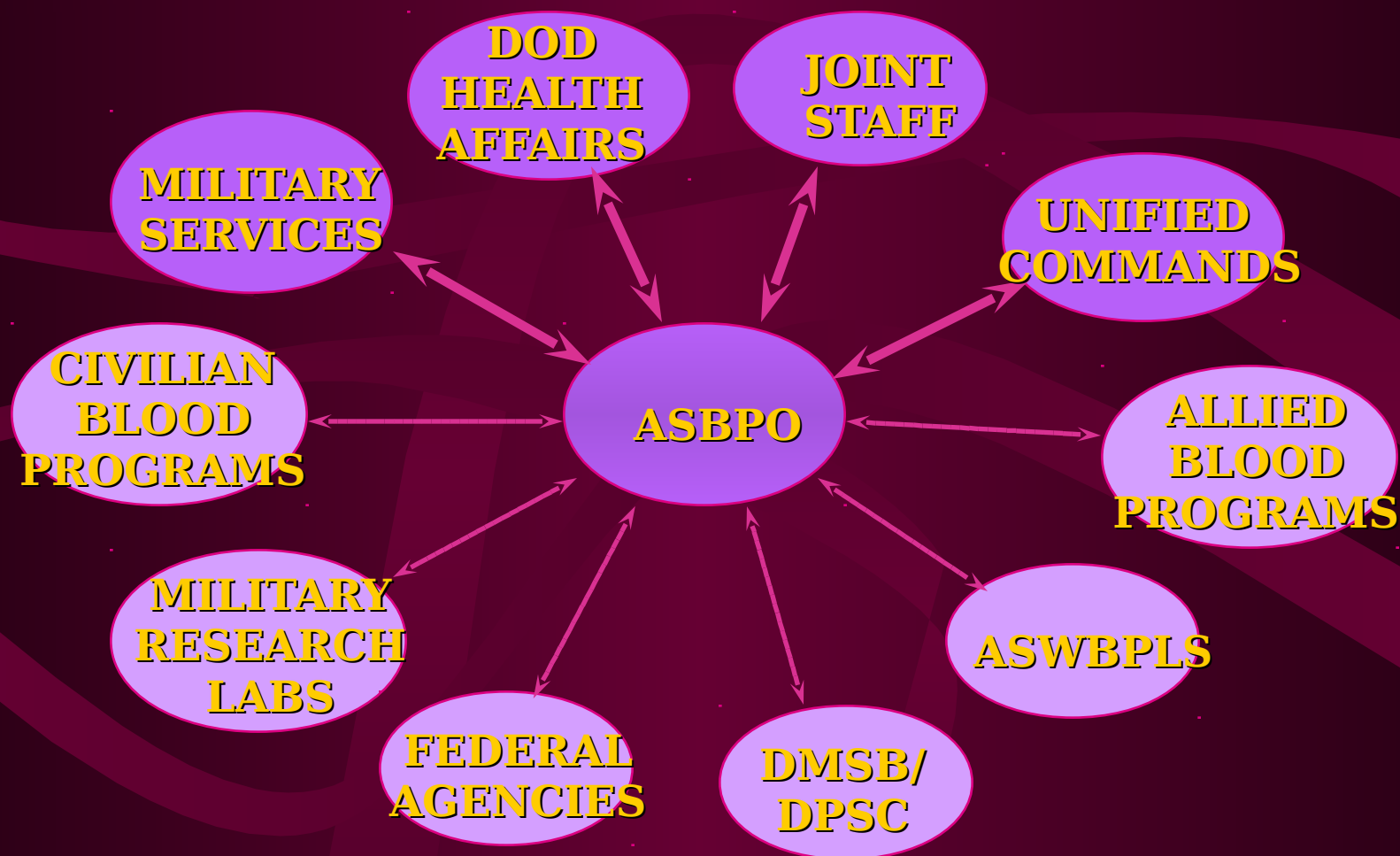
ASBPO VISION and MISSION

The Armed Services Blood Program Office, a DoD Joint Health Agency, Coordinates, for the Assistant Secretary of Defense (Health Affairs) and the Joint Staff, the Worldwide Blood Programs of the Military Departments and the Unified Commands in Peace and War. The ASD(HA) Provides Policy Guidance; the Joint Staff Gives Operational Guidance; the Army is the Executive Agent.

The Armed Services Blood Program Office (ASBPO) Through Its Coordination Role Will Ensure That Quality Blood Products, Blood Substitutes, and Blood Services are Provided to Improve Patient Care and Reduce Patient Risk for All Authorized Beneficiaries in Peace, Contingency, and War.

**ARMED SERVICES
BLOOD PROGRAM**

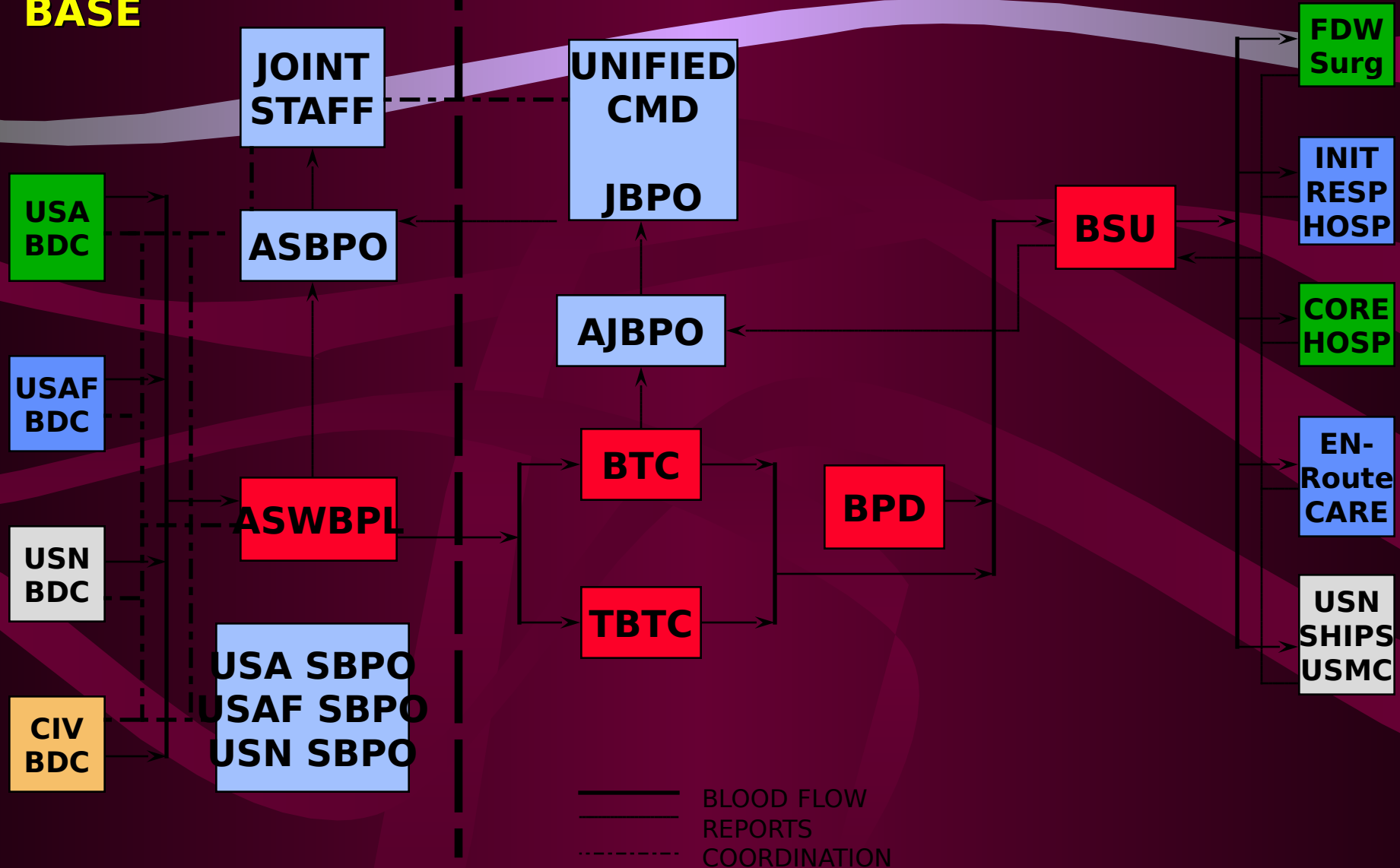
Blood Program Coordination



ARMED SERVICES BLOOD DISTRIBUTION SYSTEM

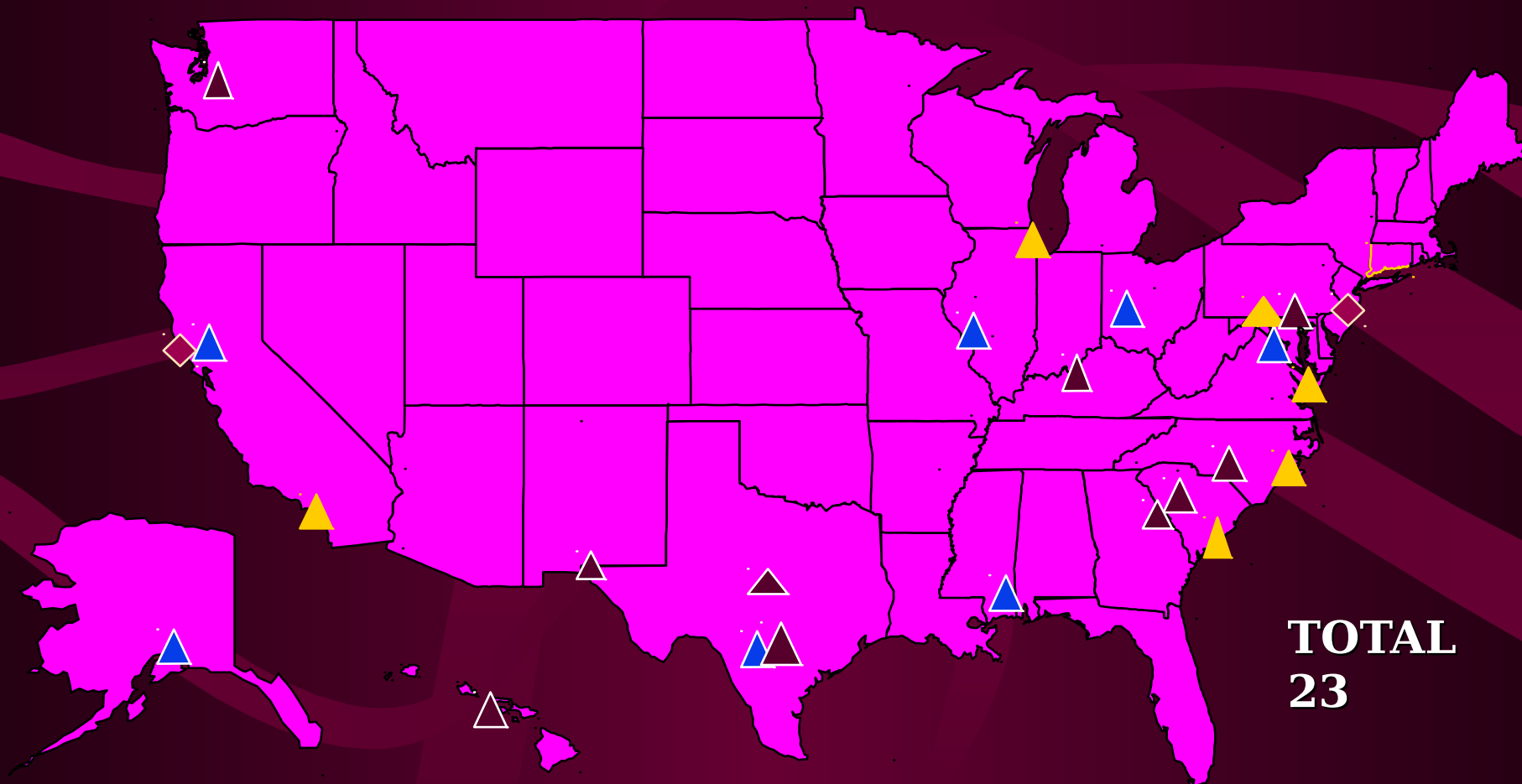
SUPPORTING BASE

THEATER OF OPERATIONS



◆ ASWBPL 2
△ USA 10
▲ USN 6
▲ USAF 7

Armed Services Blood Donor Centers



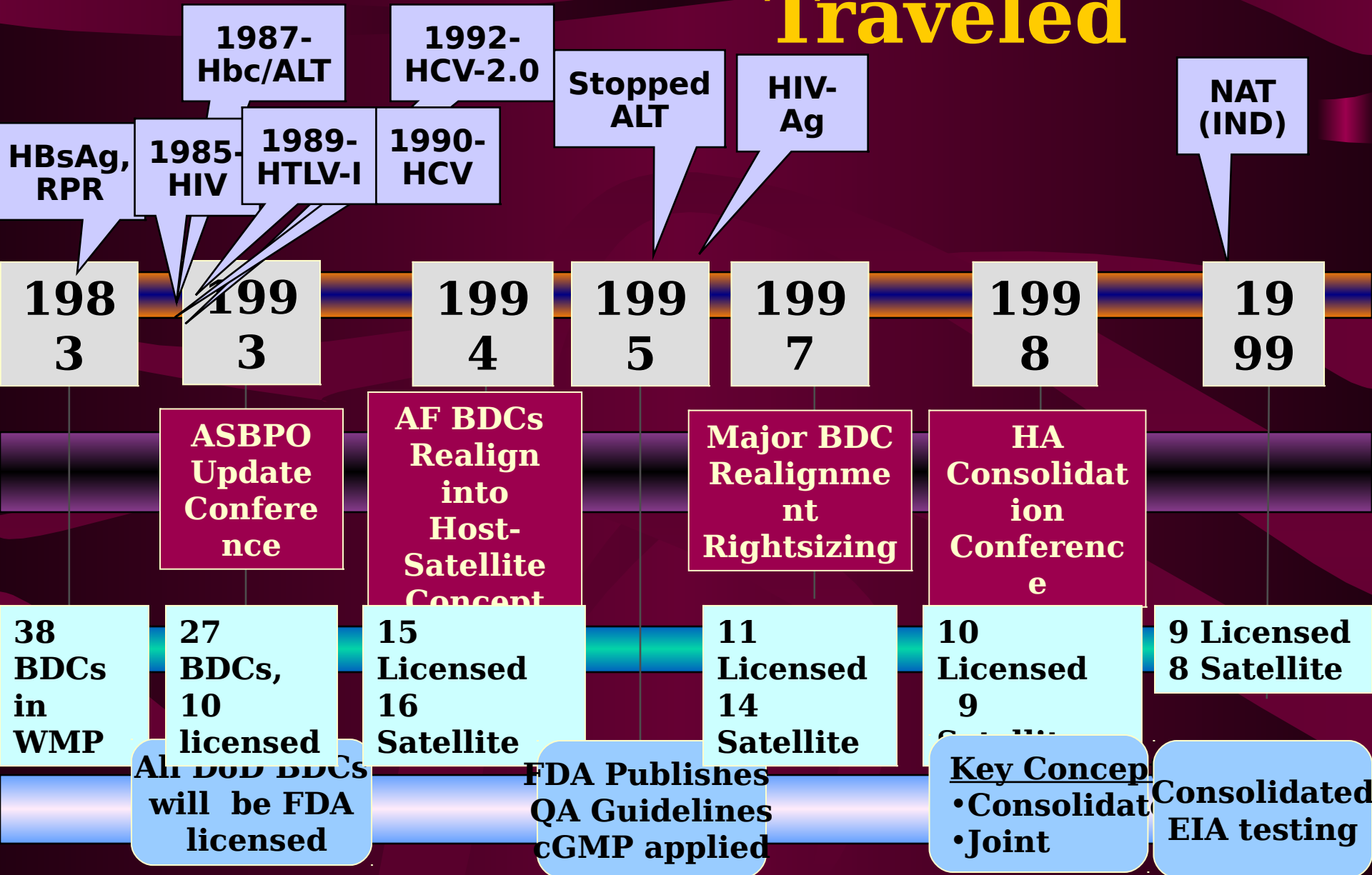
Armed Services Blood Donor Centers - Overseas

- ▲ USA 2
- ▲ USN
- ▲ USAF 3

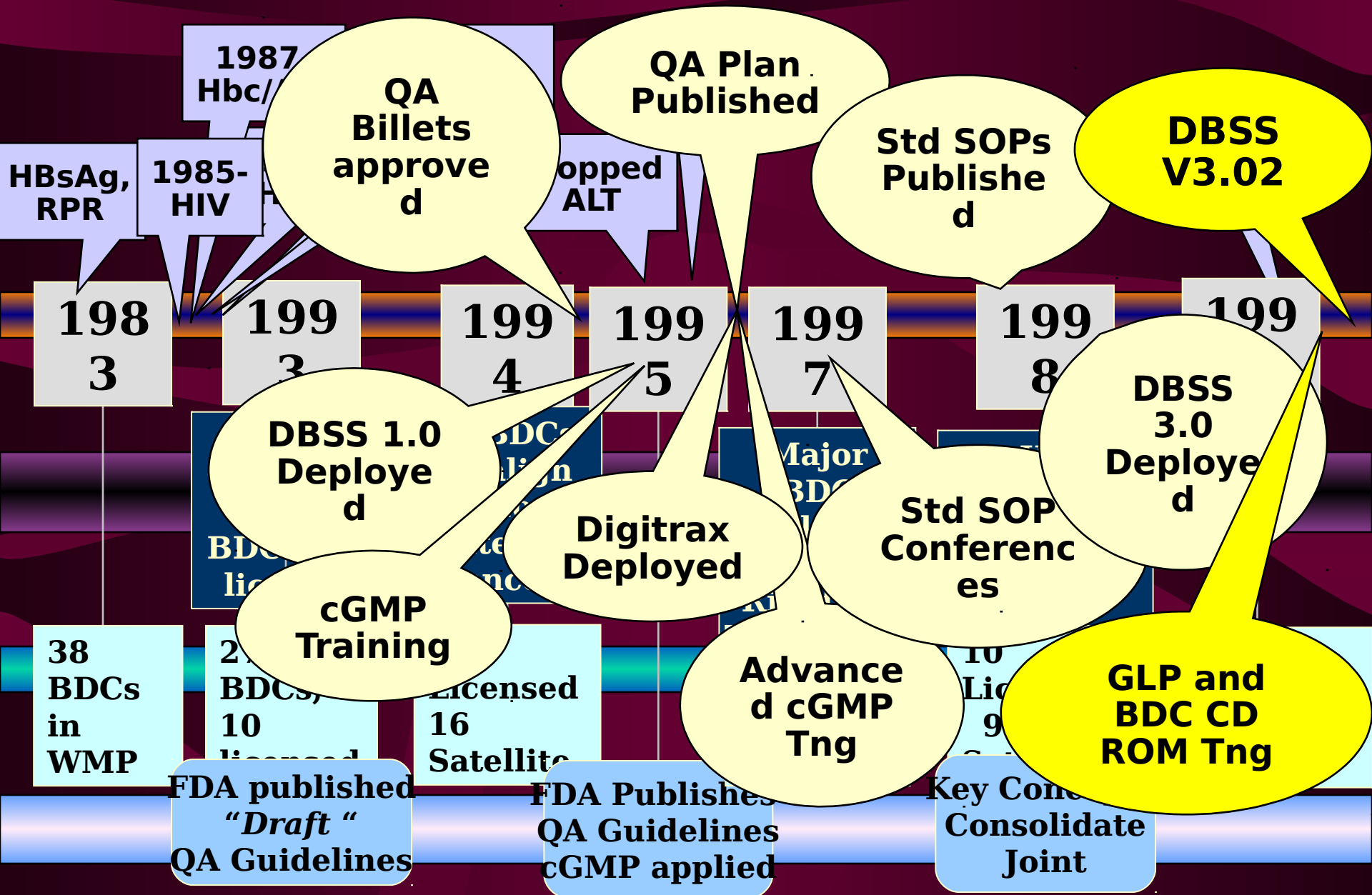


Total - 11

USAF Path Traveled



USAF Path Traveled

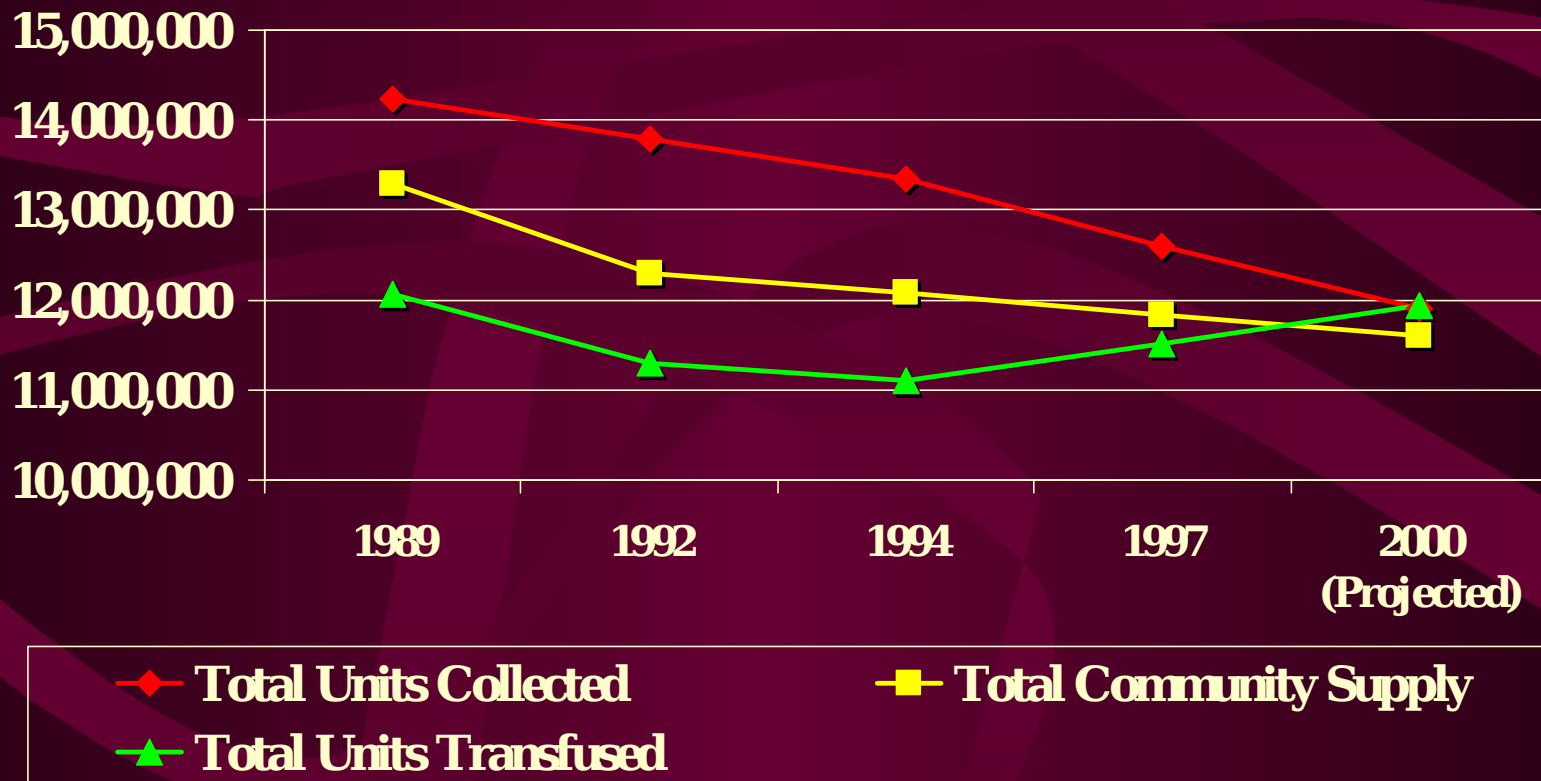




Blood Supply:

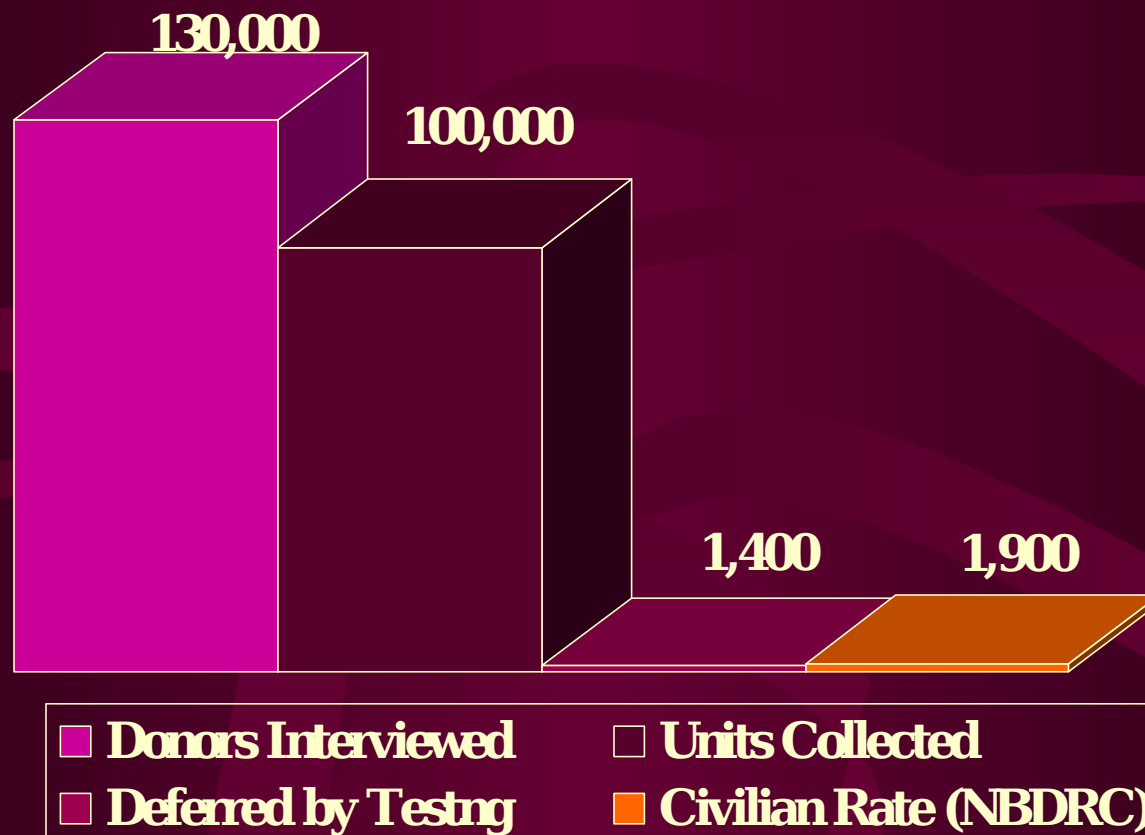
Availability of Blood

Testimony Before the Subcommittee on Oversight and Investigations,
Committee on Commerce, House of Representatives September 23,
1999



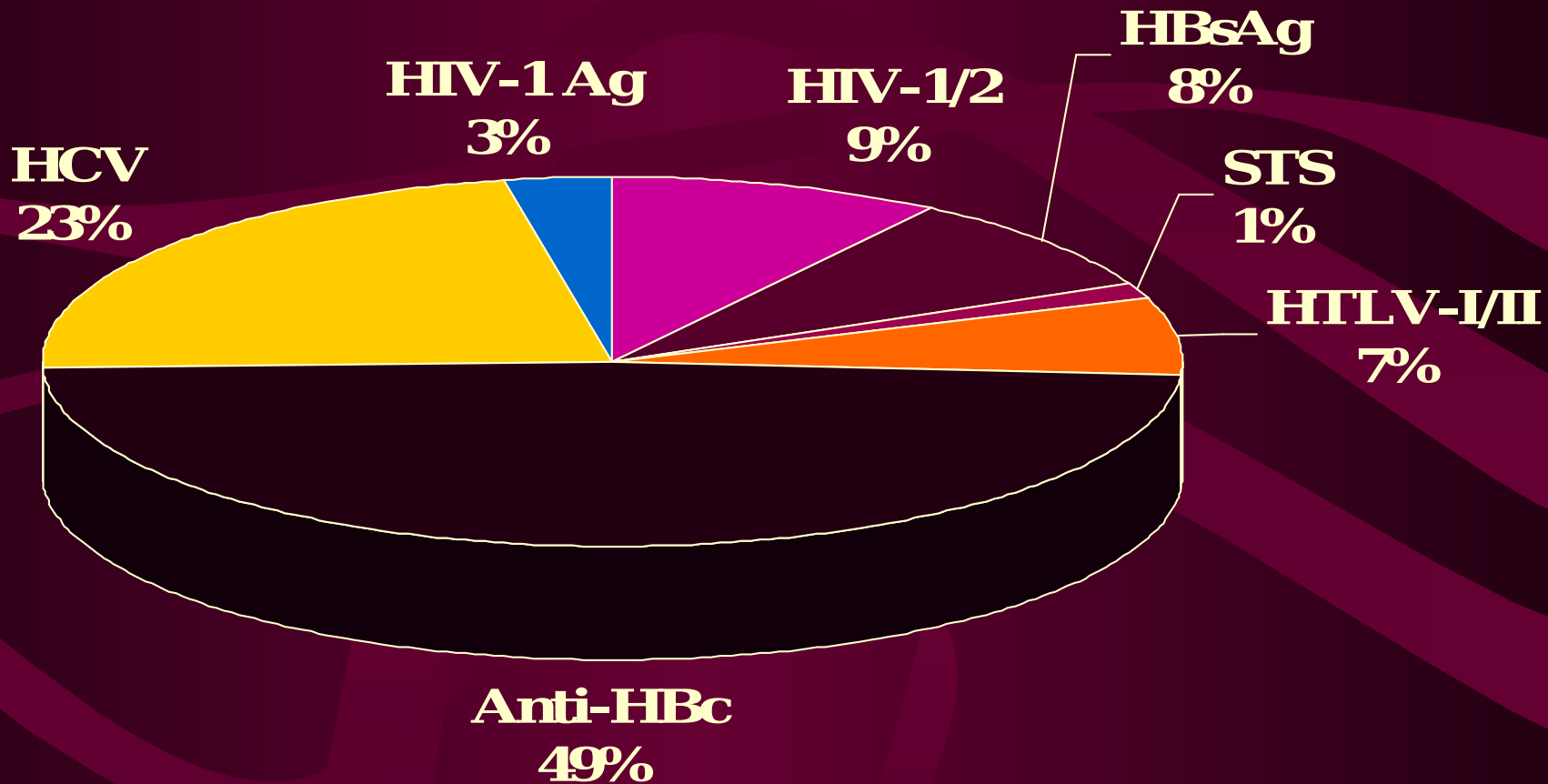


DoD Annual Averages



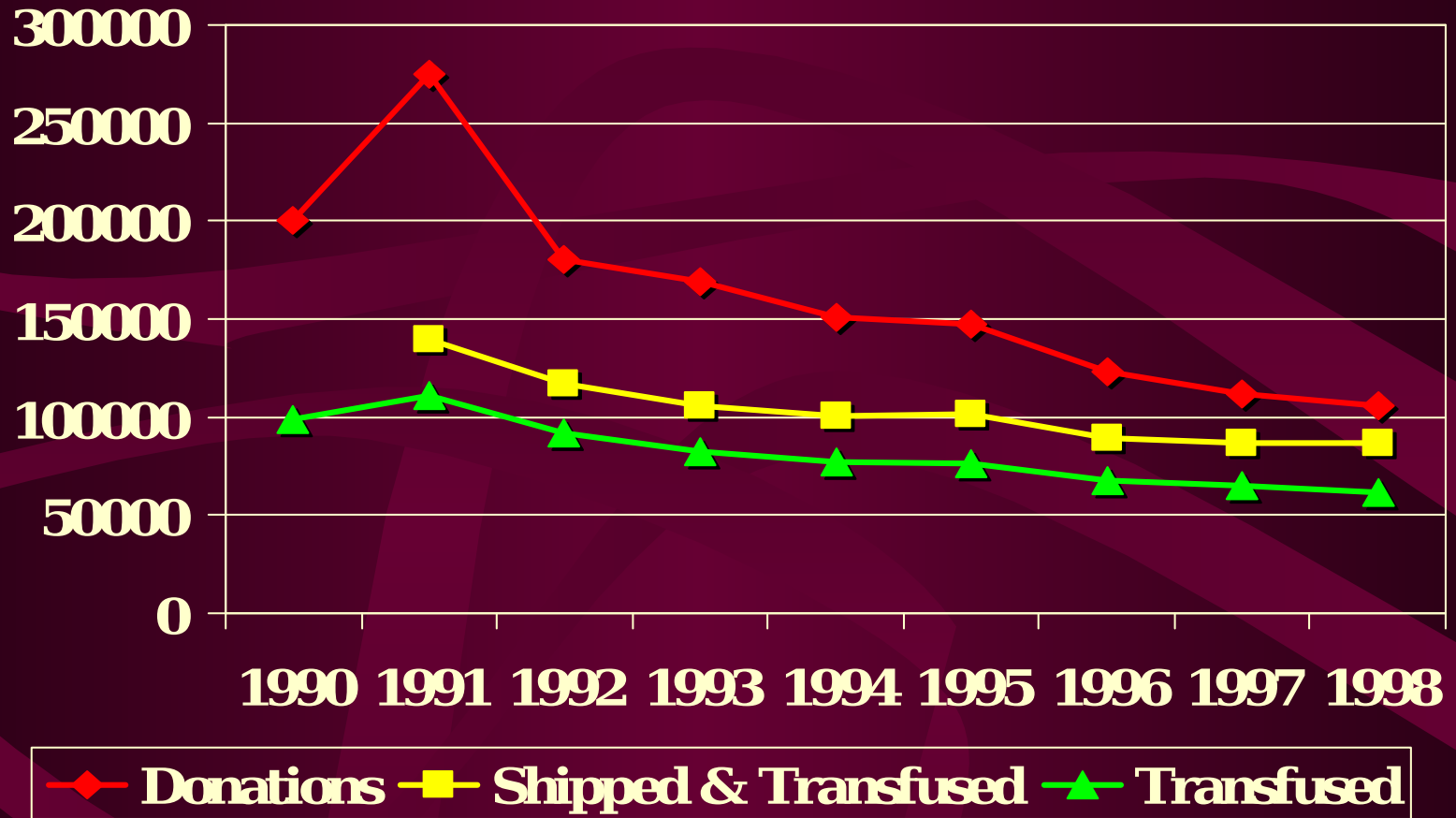


DoD Annual Deferrals



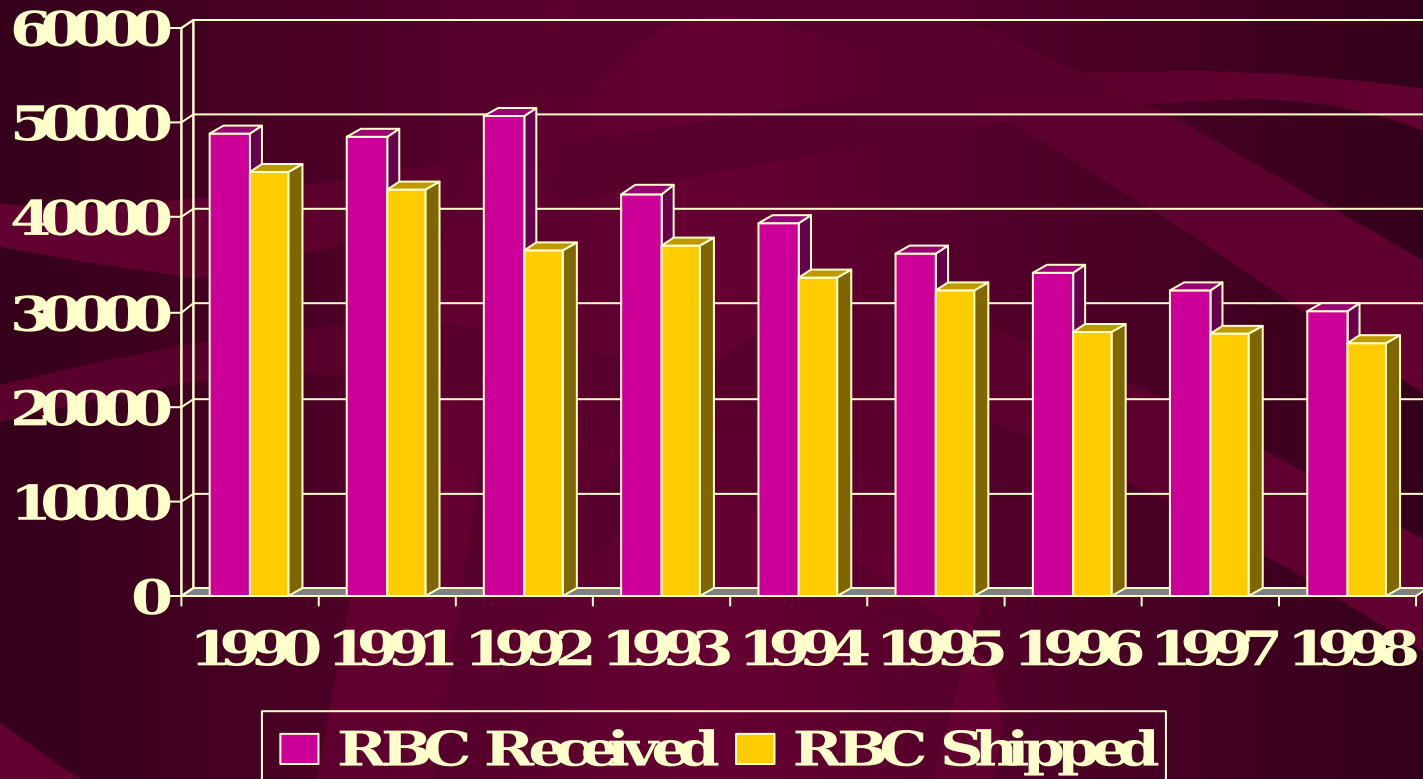


DoD USAGE





RBC From Civilians





Blood Safety Future Focus of HHS

- 10th Meeting of Advisory Committee on Blood Safety and Availability
 - Charged by Dr. Satcher, Surgeon General to focus on improving transfusion safety
 - Recommendations forwarded to Health and Human Services Secretary Shalala
 - Reducing medical errors high on Congressional agenda



Blood Safety Recommendations

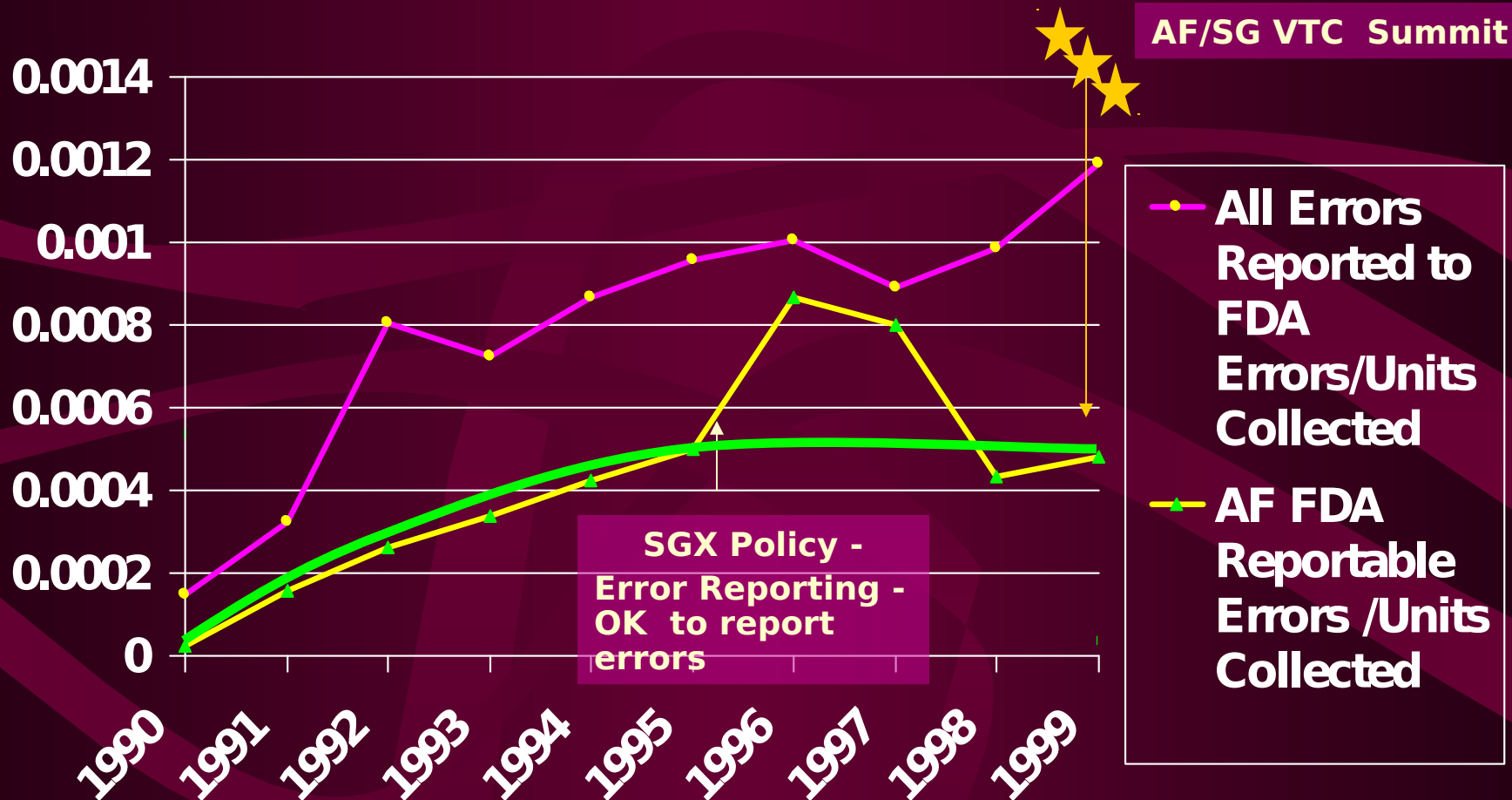
- All blood establishments should have a quality assurance program.
- Quality assurance programs in all blood establishments should capture, analyze, and respond to data on all deviations from established procedures, as well as errors and accidents, independent of whether affected blood units were distributed or caused adverse medical events.
- FDA should extend its current error and accident reporting requirements to apply to all blood establishments, including hospital transfusion services, rather than only to licensed blood establishments.



Blood Safety Recommendations

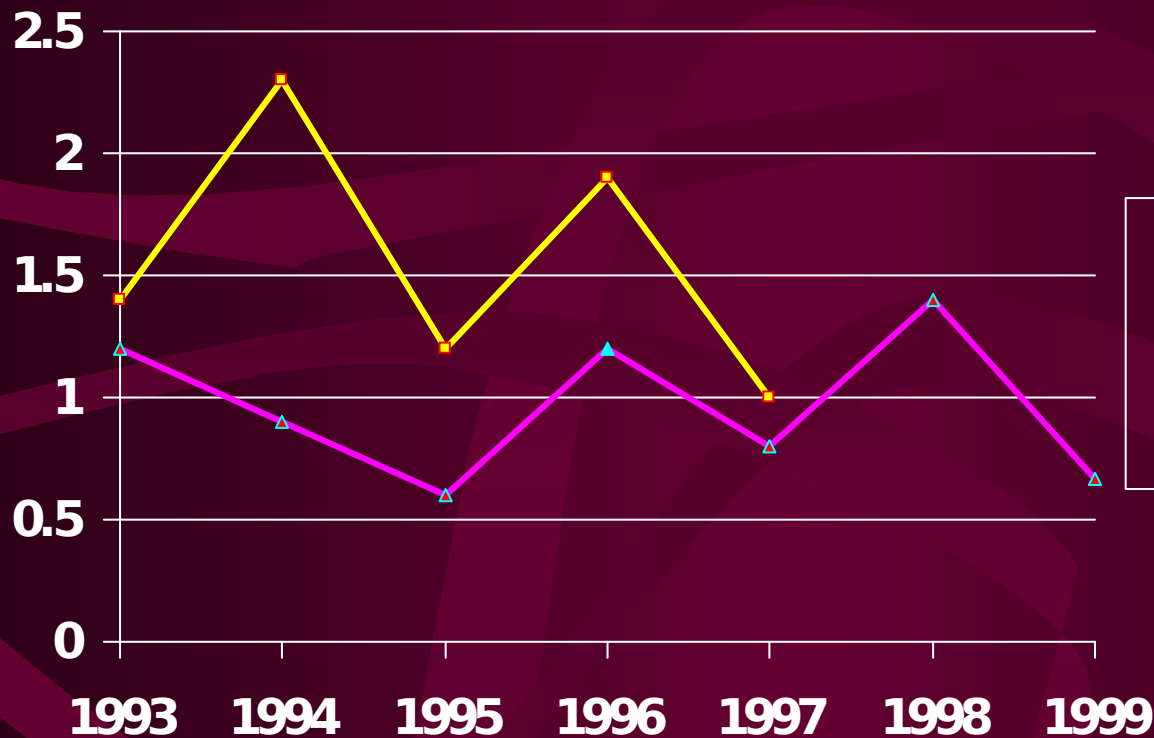
- In order to facilitate improved transfusion safety, for errors and accidents not subject to regulatory requirements, there should be established outside the regulatory framework an effective, confidential, non-punitive system for the accumulation, analysis, and dissemination of data from all blood establishments' quality assurance programs.
- Industry and government should be encouraged to facilitate the evaluation and implementation of devices that promise to prevent misidentification of blood products and/or patients

USAF FDA Reportable Error Rate # Errors/Unit Collected



by Date Error Occurred

USAF FDA 483 Observation Rate

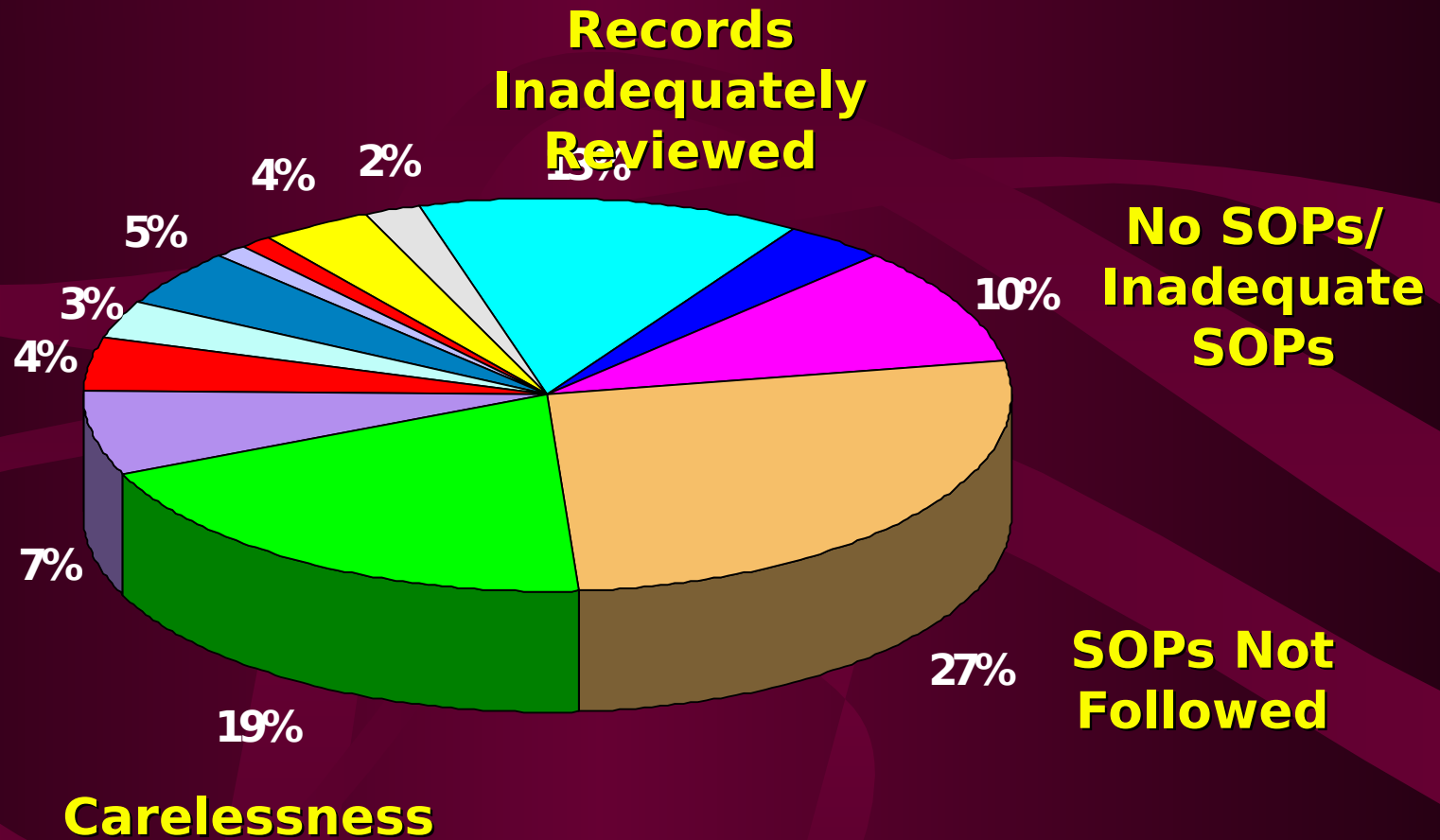


—▲— RATE/FACILITY
INSPECTED

—■— NATIONAL*

* *Citings*,
data voluntarily provided
by member organizations

USAF Contributing Factors Cited





Issues Affecting Blood Supply

- Defense Blood Standard System (DBSS)
- Malaria in Korea (BPL 99-07, 21 Oct 99)
 - 24 Month Deferral for ROK north of Seoul
- nvCreutzfeldt-Jakob Disease (BPL 99-09, Nov 99)
 - UK Donor Deferral Issued
 - UK beef in European commissaries
- Malaria in Dominican Republic (BPL 00-02)
- Nucleic Acid Testing (NAT)
- Universal Leukoreduction



Issues Affecting Blood Supply

- ASD (HA) Policy on non-US Blood
- MOUs with Civilians
- NATO Civil -Military Blood Committee Meeting
- Quality Assurance and Staffing
- Consolidation
- Exercises and Training
- Research and Development



Policy on the Use of Non-DoD, Non-US Food and Drug Administration Licensed Blood Products

- ASBPO has received a request from USEUCOM to revise this policy:
“that the standard of care for those beneficiaries who may receive a blood transfusion in a DoD medical treatment facility (MTF) is equal to that received in a MTF within the United States”.



Policy on the Use of Non-DoD, Non-US Food and Drug Administration Licensed Blood Products

- ASD(HA) policy is to test blood products received from host nation (HN) facilities in compliance with FDA and DoD guidance unless:
 - Blood supply has been evaluated and found to be “FDA equivalent” or higher in coordination with ASBPO and approved by ASD (HA).
 - Emergency use documented by attending physician. Samples from HN blood collected and tested as soon as possible.



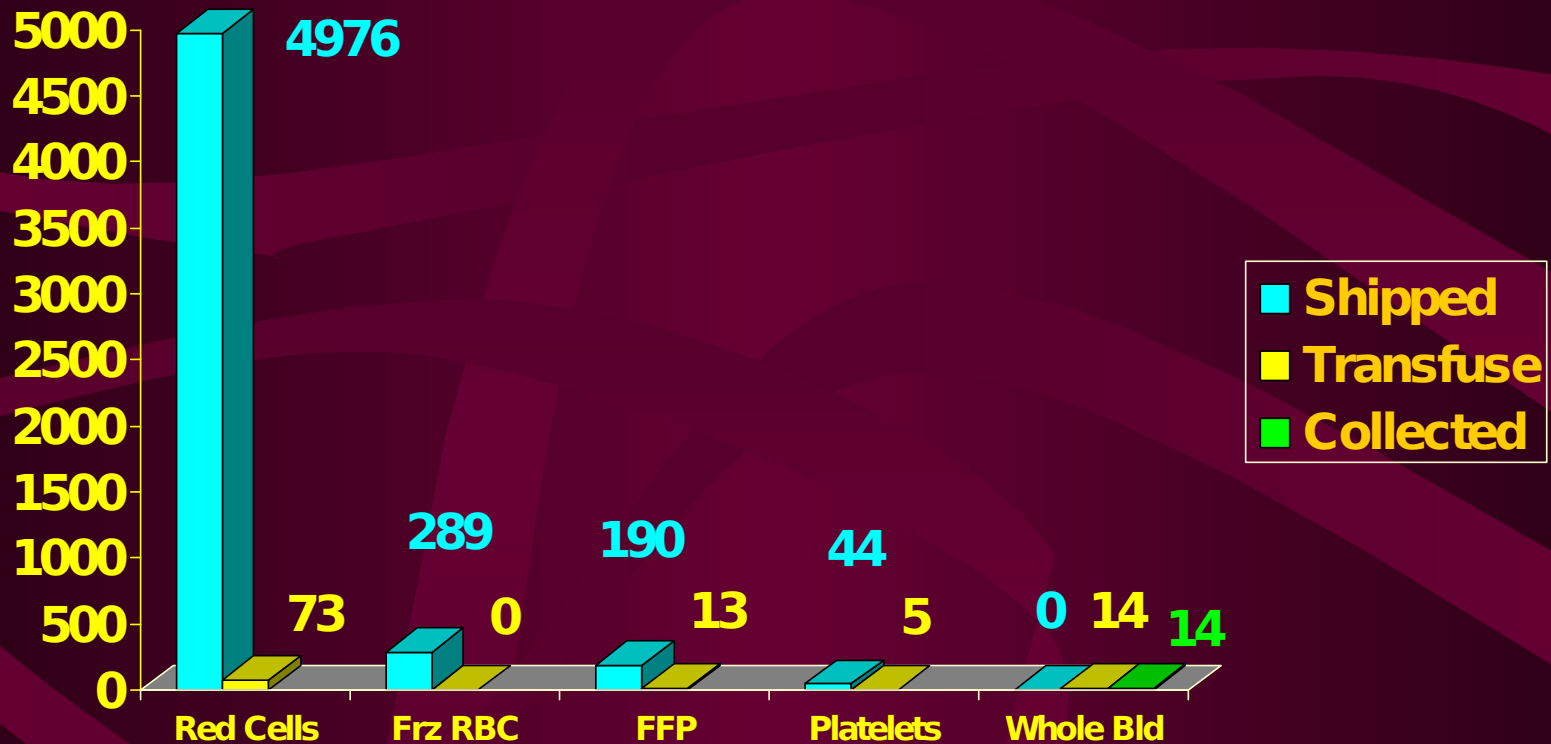
Nucleic Acid Testing - NAT

- All three services have implemented plans
 - AF has contracted with civilian donor centers
 - Army completing testing lab at Ft. Hood (ECD Mar 2000)
 - Navy to send testing to Army
- HA has provided \$1.7M funding for this testing



Bosnia - Blood Products

As of February 2000





Kosovo - Blood Products

As of February 2000





Research and Development Objectives

- Minimize blood loss
- Optimize fluid resuscitation
- Minimize or eliminate storage and transport problems
 - Develop and package oxygen-carrying and coagulant blood products



Research and Development Objectives

- Hemostatic Dressing
- Extended RBC Storage Solution
- Automated Deglycerolization with extended liquid storage
- Hemoglobin Base Oxygen carriers (HBOC)
- Lyophilized Products
- Viral and Bacteria Inactivation
- Rapid Field Testing



Blood Research & Development

- Hemostatic (Fibrin) Bandage
 - Army currently testing 8 manufacturers
 - Test results to be available in April
 - Field to be reduced to 1 or 2 for milestone 1 approval
 - 18-24 months
 - 3-5 years to production



Blood Research & Development

- FFP
 - 7-Year FFP Approved (DBSS issues)
- FROZEN RBCs
 - 15-yr. frozen red cells-under appeal
- FROZEN PLATELETS
 - Frozen platelet licensure submitted



Blood Research & Development

6% DMSO Frozen Platelets

- **Licensed Apheresis Platelets**
- **Frozen w/in 24 hrs of collection**
- **Stored for 2 years at -65 C**
- **Thawed at 42 C**
- **Washed w/platelet washing solution**
- **Resuspended in autologous platelet poor plasma**
- **Stored for 6 hours at RT**
- **70% recovery of platelets in vitro**
- **40-50% therapeutic effectiveness of fresh**
- **2.5 units frozen = 1 fresh apheresis unit**

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This concludes my briefing. Are there any